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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 24 2000 96 '00 FEB 29 P1:32

Debbie Herrington
Manager, Regulatory Affairs
Bard Electrophysiology
55 Technology Drive
Lowell, Massachusetts 01851

RE: Docket No. 99P-4108

Dear Ms. Herrington:

This responds to your letters, dated September 14, 1999 and November 1, 1999, in which you requested an exemption from the Performance Standard for Electrode Lead Wires and Patient Cables, as it applies to your firm's temporary pacing electrode catheters. I am also responding to your subsequent letter, dated January 13, 2000, in which you ask about the acceptability of your proposed universal adapter for use in converting external pacemaker generators to accept lead wires that comply with the performance standard. We believe that your proposed universal adapter can be used to convert external pacemaker generators for the reasons explained below. Based on availability of such adapters from your firm, and adapter cables available from at least one other vendor (Remington Medical), we are denying your exemption request.

In our past discussions with manufacturers and user facilities, the Office of Compliance has emphasized that an adapter needs to be secured to the device in such a way that the adapter cannot be inadvertently removed when the lead wire is disconnected. Easy removal of the adapter with the lead wire could convert a compliant lead wire back to an unsafe configuration, thus defeating the safety intent of the performance standard. FDA has generally advised manufacturers that the adapter should either be permanently attached to the device, or removable only by use of a tool.

We understand that older external pacemaker generators and some new interface cables typically have a thumbscrew, collet, or chuck that is manually tightened onto an exposed pin lead wire to secure it in place and to provide good electrical contact. The use of this same thumbscrew, collet, or chuck to manually secure an adapter to the device or to an interface cable, would meet the intent of the performance standard. In these circumstances, removal of the adapter from the device would require a conscious decision and action by the user, and would involve more than simply pulling out the lead wire.

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As you know, exposed pin lead wires may not be marketed or used after May 9, 2000, without an approved exemption or variance. The Food and Drug Administration has granted exemptions from the performance standard for all heart wires and for a few Medtronic temporary pacing electrodes that cannot comply with the performance standard. For pacemaker generators that are converted using adapters, user facilities can manually remove the adapters when they expect to use these exempted electrode lead wires and secure the adapter back onto the device for other uses. Alternatively, some pacemaker generators (e.g., Pace Medical) provide two separate sets of collets. In those cases, the user facility can use adapters for one set of collets for use with protected lead wires, while leaving the other set of collets available for use with exempted exposed pin lead wires.

In summary, we have concluded that your proposed universal adapter and similar adapters can be used to convert external pacemaker generators to accept lead wires that comply with the performance standard. Because such adapters are available, we are denying the exemption from the performance standard you requested for your firm's temporary pacing electrode catheters. I trust that this response fully addresses your concerns. If additional information is required, please contact Stewart Crumpler in our Office of Compliance at (301) 594-4659.

Sincerely yours,

S/ LZK

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health

Draft:ESCrumpler:2/4/2000
Review:CEUldriks:2/7/00

cc: HFA-305 (Docket #99P-4108)
HFA-224
HFR-NE200
HFZ-1
HFZ-3
HFZ-15 (JSheehan, MHanna, Files)
HFZ-141 (RWalchle)
HFZ-300
HFZ-305 (Precedent Correspondence)
HFZ-340 (SCrumpler, Files)
HFZ-341